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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

PARA, ANNETTE H

ART UNIT PAPER NUMBER

1661

DATE MAILED: 12/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/754,149

Applicant(s)

BRUIJN, JACOBUS DE

Examiner

Annette H. Para

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 44-47 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 44-47 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

The preliminary amendment received on January 9, 2004 has been entered.

The requirement restriction/election sent on September 15, 2006 has been withdrawn.

Claims Pending

Claims 44-47 will be examined on the merits.

Objection to the abstract

The abstract is objected because it is not drawn to the instant claimed invention.

Objection to the Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: on page 14 of the specification applicant states that the seeds had about 183 ppb of ergovaline, whereas, in the claim applicant states that the seed comprises about 55 ppb of ergovaline. The levels should agree.

Drawing

The drawing filed on 01/09/2004 is accepted.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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Claims 44-47 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 44-47 are drawn to an endophyte of a tall fescue plant and of a seed of a tall fescue. As stated in the specification (p.14, line 5), grass samples have the potential to contain endophyte. The specification does not teach any isolation of the endophyte. There is no human involvement in the manufacturing of the endophyte. Since claims 44-47 encompass products of nature, the claimed invention is directed to a non-statutory subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description

Claims 44-47 are rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 44-47 are drawn to any endophyte in a tall fescue plant or seeds herein. Not only tall fescue plants and their seeds host many different strains of endophytes (Latch et al. Mycotaxon Vol.XX,No. 2 1984. pp. 535-550; entire article) but Applicant has not isolated nor described the endophyte

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claimed. In fact, the Applicant limited himself to analyze the presence of alkaloids, thus detecting endophytes.

Therefore, given the lack of written description in the specification with regards to the isolation and description of the endophyte, it is not clear that Applicant was in possession of the claimed genus at the time this application was filed.

Enablement

Claims 44-47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. There is no statement noting that the claimed endophyte is deposited in the American Type Culture Collection under the terms of the Budapest Treaty.

If a deposit is made under the terms of the Budapest Treaty, then a statement, affidavit or declaration by Applicants, or a statement by an attorney of record over his or her signature and registration number, or someone empowered to make such a statement, stating that the instant invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If a deposit has not been made under the Budapest Treaty, then, in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and MPEP 2402-2411.05, Applicant may provide assurance of compliance by statement, affidavit or declaration, or by someone empowered to make the same, or by a statement by an attorney of record over his or her signature and registration number showing that:

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- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and,
- (d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and,
- (e) the deposit will be replaced if it should ever become unviable.

The specification teaches that endophytic funguses in the plant produce alkaloids. Two of the alkaloids produced are ergovaline and lolitrem B. Furthermore, the specification teaches a tall fescue plant and seed comprising about 55 ppb of ergovaline and <100 ppb of lolitrem B. Enablement is considered in view of the *Wands* factors (MPEP 2164.01(a)).

With regard to the level of alkaloids produced in an endophyte-infested tall fescue plant, claims 44-45 are drawn to an endophyte wherein a tall fescue plant comprising about 55 ppb of ergovaline and <100 ppb of lolitrem B.

Breath of the claims. The claims are drawn to any endophyte wherein the tall fescue plant which comprises about 55 ppb of ergovaline and <100 ppb of lolitrem B.

Working examples in the specification: There is no working example in the specification, which discloses the type of endophyte producing that level of alkaloids in plants.

Level of predictability in the art. Cultural practice greatly affects the level of alkaloids in endophyte-infected tall fescue. Tall fescue plant subjected to biweekly mowing showed an increased level of alkaloids. (Salminen et al. Journal of Chemical Ecology 2002 Vol. 28, No.5 pp. 939-950; see p.947, second paragraph). Furthermore, the level of ergovaline in all plant tissues increased with Nitrogen fertilization (Rottinghaus et al. J. Agric. Food Chem. 1991, 39,112-115; see p.114, second

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column, table II, III). Thus as shown by the art, the levels of ergovaline and of lolitrem B in endophyte-infected tall fescue plant vary tremendously.

The amount of direction provided by the specification. There is no guidance on how to maintain the level of alkaloids claimed in the tall fescue plants.

Quantity of experimentation necessary. Given the unpredictable level of alkaloids in plants exposed to different cultural practice, the amount of experimentation would be high for the skilled artisan.

With regard to claims 46-47, the claims are drawn to an endophyte in a seed of a tall fescue plant.

Breadth of the claims. The claims are drawn to any endophyte in the tall fescue seed.

Working examples in the specification: There is no working example in the specification, on how seed moisture and storage temperature affect the viability of the endophyte.

Level of predictability in the art. Seeds infected by endophytes require special storage facilities to guarantee the viability of the endophytes (Siegel et al. Ann. Rev. Phytopathol. 1987 25:293-315; see p. 309 second paragraph), thus the importance seed moisture and storage conditions.

The amount of direction provided by the specification. There is no guidance on how to store endophyte-infected seeds to keep endophyte viability.

Quantity of experimentation necessary. Given the importance of the moisture and temperature on endophyte viability, the amount of experimentation would be high for the skilled artisan.

In view of the afore-mentioned reasons, it would require undue experimentation for one skilled in the art to make and use the full scope of the claimed invention.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 44-47 are rejected under 35 U.S.C.102 (b) as being clearly anticipated by Siegel et al. (Journal of Chemical Ecology, Vol. 16 No. 12, 1990), taken with the evidence of Salminen et al. and Rottinghaus et al. Claims are drawn to an endophyte of a tall fescue plant wherein the tall fescue plant or a seed of a tall fescue which comprises about 55 ppb of ergovaline and < 100 ppb of lolitrem B.

Siegel et al. teach an endophyte of a tall fescue plant or a seed of a tall fescue plant (page 3303, second paragraph). The tall fescue plant comprises 44 ppb of lolitrem B, less than 100 ppb, and 1.3 ppb of ergovaline (page 3308, Table 1, Plant 12), which can rise to about 55 ppb during the course of the day, when levels vary under different cultural practices. The seeds of the tall fescue plant inherently comprise the same level of alkaloids, absent evidence to the contrary.

Summary

No claim is allowed.

Future Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette H. Para whose telephone number is (571) 272-0982. The examiner can normally be reached Monday through Thursday from 5:30 a.m. to 4:00 p.m.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975. The fax number for the organization where the application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either the Private PAIR or the Public PAIR. Status information for unpublished applications is available through the Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "A. H. Para", enclosed within a hand-drawn oval.

Annette H Para

11/17/2006